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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/270,006    03/16/99    ROBIN    J    017753-113

021839    HM12/0223  
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EXAMINER

BALASUBRAMANIAN, V

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1611

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DATE MAILED:

02/23/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/270,006

Applicant(s)

Robin et al.

Examiner  
V nkataraman Balasubramanian

Group Art Unit  
1611



☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-87 \_\_\_\_\_ is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-87 \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## DETAILED ACTION

### *Election/Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-21, 24, 33-37, 40-49 and 54-58, drawn to a compound namely, side chain bearing cephalotaxine of formula  $\Omega$ -CO-OCTX wherein the side chain is a substituted heterocycloalkane of formula shown in claim 1, entry 1 and a process for the preparation, classified in class 548, subclass 408 and also depending upon the side chain in classes various, subclasses various, depending upon preferred embodiment of Z and n.
- II. Claims 1-21, 25-26, 35-36, 38, 40-49 and 54-58, drawn to a compound namely, side chain bearing cephalotaxine of formula  $\Omega$ -CO-OCTX wherein the side chain is a substituted linear alkane of formula shown in claim 1, entry 2 and a process for the preparation, classified in class 548, subclass 408.
- III. Claims 1-21, 27-33, 34, 36 and 39-49, drawn to a compound namely, side chain bearing cephalotaxine of formula  $\Omega$ -CO-OCTX wherein the side chain is a substituted heterocycloalkane of formula shown in claim 1, entry 3 and a process for the preparation, classified in class 548, subclass 408 and also depending upon the side chain in classes various, subclasses various, depending upon preferred embodiment of Z, Q<sup>1</sup>, Q<sup>2</sup> and n.

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- IV. Claims 22-23, drawn to alkaline metal alkoxide of cephalotaxine, classified in class 548, subclass 408.
- V. Claims 50-53, drawn to compounds namely various chiral esters, classified in class various, subclass various depending upon the structure of the chiral ester.
- VI. Claims 59-71, drawn to compounds namely, tertiary cycloalkane carboxylic acids which are used as side chain, classified in class various, subclass various depending upon the preferred embodiment.
- VII. Claims 72-78, drawn to compounds namely, tertiary alkene carboxylic acids which are used as side chain, classified in class 560, subclass various depending upon the preferred embodiment..
- VIII. Claims 79-84, drawn to mixed anhydrides of side chain acids, classified in class 560, subclass various depending upon the preferred embodiment.
- IX. Claims 85-87, drawn to process for purification of side chain bearing cephalotaxine, classified in class 548, subclass 408 and also in classes various, subclasses various, depending upon preferred embodiment of Z and n..

The inventions are distinct, each from the other because of the following reasons:

Inventions of group I, II and III are independent and distinct from each other because they are directed to dissimilar compounds with varying side chain cores such as heterocycloalkane of varying hetero atoms and ring size versus linear alkane versus heterocycloalkane having more than one hetero atoms including silicon and phosphorous as well as varying ring size. Consequently, the

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groups have different classifications and require separate prior art searches. Art which may render obvious or anticipate one of the groups would not necessarily do the same for the other group. Each can support a patent as the compounds of each group are capable of being utilized alone not in combination with other members listed in the Markush group.

Inventions I-III and IV-VIII are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate products (invention II) is deemed to be useful for making other esters and derivatives of cephalotaxine including chiral esters as evidenced in the references cited in the Information Disclosure Statement as well as US 4,203,996 and hence the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Inventions I-III and IX are related as product made and a process of purification. There is no required combination. The compound of Group I-III may be purified by a process other than the process of invention IX. There is two way distinctness as the compound (Group I-III) may be purified

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by more than one method as evidenced by the prior art stated above (and instant claims) and chromatographic procedure of invention IX can be used for other cephalotaxine esters cited in the prior art stated above.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the search required for Group II and III is not required for Group V-VIII , restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Due to distinct nature of each of the inventions, a restriction is set forth in writing.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian ( Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on weekdays from 8.30 AM to 5.00 PM.

The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

VB

V. Balasubramanian (Bala)

2/18/2000

*Mukund J. Shah*

MUKUND J. SHAH

SUPERVISORY PATENT EXAMINER

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